

# Notice of Allowability

Application No.

10/656,895

Examiner

Stephen L. Rawlings, Ph.D.

Applicant(s)

WALDMAN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12 October 2006.
2. ☒ The allowed claim(s) is/are 1 and 3.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date See Continuation Sheet
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20070207.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

  
Stephen L. Rawlings, Ph.D.  
Primary Examiner  
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Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 20040224;20060503;20061013.

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Mark DeLuca on February 7, 2007.
3. The application has been amended as follows:

In the specification:

The paragraph beginning in line 2 at page 12 of the specification has been replaced with the following:

Figure 1 shows the nucleotide sequence of the human ST receptor mRNA, GeneBank GenBank™ Accession #S57551, which is ~~incorporated~~ incorporated herein by reference (SEQ ID NO: 82). The gray shaded area is the sequence deleted in CRCA-1 ~~transcript~~ transcript including ~~on to~~ one of the two boxed "GG" sequences or one G from each box. The start codon, ATG, which is nucleotides 118-119-120 of the sequence is the ~~initiation~~ initiation codon for ST receptor protein expression. The CRCA-1 transcript is missing a 142 nucleotide sequence spanning nucleotides 192-333, 193-334 or 194-335. Thus unique sequences of the CRCA-1 protein not found ST receptor mRNA include nucleotides 191-192-193-336, 191-192-335-336 or 191-334-335-336 as set forth in FIG. 1 or using corresponding numbers from sequences set forth in the sequence listing. These 4 nucleotide sequences are all identical, A-G-G-C, and correspond to nucleotides 110-111-112-113 of SEQ ID NO:1

In the claims:

Claim 1. (Currently Amended) An *in vitro* method of determining whether or not an individual has metastasized colorectal cancer cells comprising the steps of examining a sample of lymph node tissue ~~the steps of examining a sample of lymph node tissue~~ from an individual to determine whether CRCA-1 mRNA is present in said sample wherein the presence of said CRCA-1 mRNA is indicative of the presence of metastasized colorectal cancer cells in said sample, wherein said CRCA-1 mRNA comprises the ribonucleotide sequence corresponding to the deoxyribonucleotide sequence of the complementary DNA (cDNA) molecule of SEQ ID NO: 1, which was generated from said mRNA.

Claim 2. (Canceled).

Claim 3. (Previously Presented) The method of claim 1 wherein the presence of said CRCA-1 mRNA in said sample is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify said CRCA-1 ~~transcript~~ mRNA or cDNA generated therefrom.

Claims 4-54. (Canceled).

***Examiner's Statement of Reasons for Allowance***

4. The following is an examiner's statement of reasons for allowance:

The prior art does not teach or reasonably suggest the association between the presence of the CRCA-1 mRNA in lymph node tissue of an individual and the presence in the lymph node of the individual of metastatic colorectal cancer cells.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Oath/Declaration***

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

(a) Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

(b) It was not executed in accordance with either 37 C.F.R. § 1.66 or 1.68 by Joshua M. Pearlman.

***Conclusion***

7. Claims 1 and 3 have been allowed.

8. Claims 1 and 3 have been renumbered as claims 1 and 2, respectively.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Stephen L. Rawlings, Ph.D.  
Primary Examiner  
Art Unit 1643

slr  
February 12, 2007